August 28, 2017

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1810

Re: CMS-1674-P; Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program; 82 Fed. Reg. 31190 (July 5, 2017)

Dear Administrator Verma:

On behalf of the American Nephrology Nurses Association (ANNA), I am writing to share our comments on the proposed rule for the “Medicare Program; End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI), and End-Stage Renal Disease Quality Incentive Program (QIP).”

ANNA is the professional association that represents nurses who work in all areas of nephrology. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 8,500 registered nurses (RNs) in more than 90 local chapters across the United States. Members practice in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis units, hospital outpatient units, and hospital inpatient units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.
ANNA Comments on CMS-1674-P
August 28, 2017

ANNA is a member of Kidney Care Partners (KCP) and the Alliance for Home Dialysis and has actively participated in the development of their comment letters. The following comments are in addition to the comments submitted to the Centers for Medicare and Medicaid Services (CMS or Agency) by KCP and the Alliance for Home Dialysis.

I. Calendar Year (CY) 2018 ESRD PPS

Provisions of the Proposed Rule

Pricing Eligible Outlier Drugs and Biologicals That Were or Would Have Been, Prior to January 1, 2011, Separately Billable Under Medicare Part B

ANNA supports the Agency’s proposal to use the Social Security Act 1847A pricing methodologies for eligible drugs and biologicals under the ESRD PPS outlier drug policy. However, we join with KCP in stressing the importance of the pricing methodologies not creating barriers to these essential medications. ANNA believes strongly that a policy that in any way impedes the ability of patients to access outlier drugs will result in substandard care. While we understand the importance of being mindful of cost containment, these policies must balance cost reduction with access to needed medications. Patients who require outlier drugs should not be denied the individualized care they need and deserve due to revisions to the pricing methodology.

Proposed CY 2018 ESRD PPS Update

CMS proposes to set the ESRD PPS base rate for CY 2018 at $233.31, which reflects a reduced market basket increase from the current base rate of $231.55. ANNA joins with the broader kidney community in supporting the Agency’s continued efforts to update the ESRD PPS, but we remain concerned about payment policies that could result in limiting the needed resources to ensure the provision of high-quality care.

Wage Index

While ANNA generally supports the wage index methodology, we are concerned about the potential impact on nephrology nurses. The wage index policy could unfortunately result in the inability to offer competitive wages to recruit and retain experienced RNs in outpatient dialysis facilities, which could result in nurses leaving the profession through no choice of their own at a time when their expertise is needed the most. Similarly, at a time of a nursing shortage, it is important there are no inappropriate financial
disincentives for younger RNs who are considering nephrology, especially in light of the critical need that will be present for these nurses as our older nurses retire.

II. CY 2018 Payment for Renal Dialysis Services Furnished to Individuals With AKI

ANNA is pleased that CMS decided to include the AKI payment rate in the proposed rule. We agree with the broader kidney community that dialysis facilities are ideally suited and prepared to treat AKI patients. As ANNA has stated in previous letters, we appreciate the Agency’s recognition of the significant differences in care requirements that exist between the ESRD and AKI patient populations.

As the Agency has indicated, the unique and distinct characteristics of the ESRD and AKI patient populations require certain critical differences in treatment protocols to achieve improved health outcomes in each respective population. Indeed, as the Agency clearly stated in the 2017 ESRD PPS and QIP final rule: “We continue to believe ... that AKI patients have various treatment needs and outcomes that may not be the same as an ESRD patient. We acknowledge that this distinction between the two populations is important.” ANNA wishes to emphasize the critical role of nephrology nurses and the increased responsibilities that are placed on them when treating AKI patients. Specifically, nephrology nurses must employ more intensive oversight and enhanced intervention when treating AKI patients compared with treating an established ESRD patient. For example, AKI patients require more vigilant monitoring, particularly in infection prevention, blood pressure control, more frequent laboratory testing, additional medication administration, and increased educational needs. The care of an AKI patient often requires more coordination of the interdisciplinary team. These are not patient care responsibilities that can be delegated to technicians or other staff; only specialized nephrology nurses can provide the type of highly intensive and coordinated care that is necessary for these patients to achieve improved health outcomes. Given the increased nursing time required to provide high-quality care to AKI patients, ANNA strongly urges CMS to recognize the specialized high-quality nursing care that nephrology nurses offer as it develops future AKI payment policy.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year 2021

ANNA appreciates the opportunity to provide comments on the QIP section of the proposed rule. ANNA has been a strong supporter of the QIP and we have been actively engaged in the implementation process of the program since its creation.

The rise in number and complexity of the ESRD QIP measures have imposed significant financial and administrative burdens on facilities and their staff members, including nephrology nurses, to collect and submit data. For that reason, ANNA encourages CMS to abstain from creating new measures and to focus on ensuring that the current set of quality measures are evidence-based, promote the delivery of high-quality care, and improve patient outcomes. As the Agency continues to add new measures into the QIP that facilities are required to meet, the growing number of metrics dilutes the more important measures (the “measures that matter”) and the ability of the facility and its staff to ensure that resources are available to focus on the delivery of patient care that can improve quality of care and patient health outcomes. This is an unintended consequence that neither CMS nor providers of care to ESRD patients desire.

We reiterate KCP’s and the Alliance for Home Dialysis’ comments on the proposals to improve the ESRD QIP, and we encourage CMS to continue working with Kidney Care Quality Alliance (KCQA) and the Nursing Community when developing and implementing quality measures.

Accounting for Social Risk Factors in the ESRD QIP Program

ANNA appreciates the opportunity to provide recommendations on how the Agency might account for socioeconomic demographic factors (social risk factors) in the ESRD QIP. We join with KCP in supporting CMS’ recognition of the unique treatment needs and challenges of beneficiaries with social risk factors and the incorporation of such risk factors in the QIP as appropriate through adjustors and other mechanisms. We agree with the Agency that accounting for social risk in the QIP should not mask any poor quality of care given by providers. ANNA looks forward to working with the Agency and other stakeholders on the issue of accounting for social risk factors and reducing health disparities in the Medicare ESRD program.

Proposed Change to the Performance Score Certificate for Payment Year (PY) 2019

ANNA appreciates the opportunity to provide comments on the QIP section of the proposed rule. ANNA has been a strong supporter of the QIP and we have been actively engaged in the implementation process of the program since its creation.
ANNA supports the public reporting of meaningful information to allow ESRD patients to make informed decisions about their care. However, we agree with concerns expressed by the kidney community about the proposed changes to the Performance Score Certificate (PCS), and we support maintaining the current PCS.

**Proposed Requirements Beginning With the PY 2020 ESRD QIP**

ANNA joins with KCP in encouraging CMS to adopt a specific set of global exclusions that would automatically be applied to all measures. Specifically, ANNA has been a strong supporter of a global exclusion for beneficiaries who receive fewer than seven treatments in a month.

**Solicitation of Comments on the Inclusion of AKI Patients in the ESRD QIP**

ANNA concurs with the provision of care to AKI patient in outpatient dialysis clinics, and we appreciate that the Agency has provided a payment mechanism for care of these patients in dialysis clinics. We also support the Agency’s efforts to ensure that AKI patients receive high-quality care in the outpatient dialysis facility setting, and we look forward to working with the Agency to establish an appropriate monitoring program that is specifically tailored to AKI patients. However, we agree with the kidney community that it would not be appropriate for the Agency to use any of the current ESRD quality measures, modify any existing ESRD measures, or create new AKI-specific measures for inclusion in the ESRD QIP.

ANNA wishes to emphasize that AKI patients are unique and distinct from ESRD patients, and therefore none of the existing QIP measures or modifications to those measures are appropriate for inclusion in the QIP. Unlike ESRD, where patients receive a chronic, on-going course of life-sustaining dialysis, the primary objective for treatment of AKI patients is to stabilize their kidney function and transition them entirely off dialysis treatment. Indeed, as noted above, the Agency clearly stated in the 2017 ESRD PPS and QIP final rule “that AKI patients have various treatment needs and outcomes that may not be the same as an ESRD patient[s]. We acknowledge that this distinction between the two populations is important.” As such, ANNA urges the Agency to maintain its previously stated position that ESRD quality measures in the QIP are irrelevant and should not apply to AKI patients.

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Proposed Changes to the Extraordinary Circumstances Exception (ECE) Policy

ANNA agrees with the points made by KCP concerning the ECE policy. We believe that dialysis camps that choose to be Medicare certified should not have to participate in the QIP, given their very limited operating schedules.

Continuation of Data Validation Studies

ANNA joins with the broader kidney community in expressing our concern that CMS has not released the validation studies of CROWNWeb or the National Healthcare Safety Network (NHSN) Bloodstream Infection Clinical Measure. Further, we too believe that CMS should not include the NHSN Bloodstream Infection Clinical Measure in the ESRD QIP until the data has been validated; without data validation, it is not appropriate to hold providers accountable for performance on this measure. ANNA urges CMS to provide an explanation in the final rule on the status of these validation studies.

Proposed Changes to Measures in PY 2020

Dialysis Adequacy Measure

ANNA has been supportive of individual dialysis adequacy measures in previous comment letters, and we continue to believe in the importance of such measures. However, we agree with concerns expressed by KCP that pooling measures may lead to unintended consequences. For example, in a freestanding home-only program, the blended rate often includes a lower percentage for home hemodialysis (HD) and a higher percentage of peritoneal dialysis (PD). With no in-center program to increase the percentage of HD, the PD adequacy may adversely impact that clinic’s overall score. If a PD patient forgets to bring samples that are required for scheduled adequacy testing, it may take as much as three months of follow-up to get that testing completed, and these delays can adversely impact the center’s score.

Clarification on VAT Measures

ANNA supports the inclusion of the proposed new vascular access measures, and we encourage the Agency to further clarify the specific guidelines for the use of these measures in the QIP. ANNA has long believed in the clinical benefits of eliminating catheters, and we join with KCP in urging CMS to weight the Catheter VAT measure more than the Fistula VAT measure. Such
weighting would further the Agency’s and kidney community’s goal to decrease the use of catheters.

**NHSN BSI Measure**

ANNA supports inclusion of NHSN BSI as a reporting measure and does not support the additional inclusion of this as a clinical measure in the QIP. As reported by CMS and the Centers for Disease Control, the data being submitted for the NHSN BSI clinical measure is neither valid nor reliable. It is not acceptable to ANNA as a performance measure until those issues are addressed.

**NHSN Healthcare Personnel Influenza Vaccination Reporting Measure**

ANNA has been a longtime supporter of the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure. However, we remain concerned that the dates of vaccine availability do not coincide with the dates for the measure. ANNA encourages CMS to modify the measure to align with the Centers for Disease Control’s guidelines for immunization, which define the performance period as October 1 or “whenever the vaccine became available.”

**KCQA NQF-Endorsed Ultrafiltration Measure**

ANNA was involved in the development of the KCQA NQF-endorsed measure on ultrafiltration, and we stated our support for the inclusion of the measure in previous comment letters. We commend CMS for including it in the QIP.

**ICH CAHPS**

ANNA has previously expressed in other comment letters our support of the ICH CAHPS as a reporting measure and our opposition to its use as a clinical measure. We continue to have concerns that the twice-annual survey requirement and the length of the survey place a burden on patients and result in fatigue, limiting feedback on their patient experience. ANNA urges CMS to reconsider the requirement for two surveys annually and permit administration of the survey once each year.

ANNA supports efforts by CMS to develop a survey to capture the experience of home patients. We agree with the Alliance for Home Dialysis
that quality measures should not exclude any set of patients from participation.

Pain Assessment

ANNA understands the need to include pain assessment as part of the evaluation of every ESRD patient. However, it is unclear why the Agency has chosen to require submission of data for this assessment twice per year when this evaluation should be conducted by nephrology nurses at every treatment. ANNA believes that documenting the pain assessment twice per year is not directly related to the provision of quality care by the dialysis clinics, and we encourage CMS to remove this requirement.

Proposed Requirements for the PY 2021 ESRD QIP

ANNA is generally supportive of most of the measures in the QIP, and our concerns regarding specific measures can be found in the previous section of this letter. ANNA joins with KCP in urging CMS to consider and include the recommendations set forth for the quality measures under the PY 2020 measures before including those measures in the QIP for PY 2021. Specifically, ANNA reiterates our support for greater weight for the measure of catheters remaining longer than 90 days in the VAT and changing the performance period in the requirements for the NHSN Healthcare Personnel Influenza Vaccination measure.

IV. Request for Information on Medicare Flexibilities and Efficiencies

ANNA appreciates the opportunity by CMS to provide recommendations on how to create more flexibility and efficiency in the Medicare ESRD PPS and QIP and to reduce the unnecessary financial and administrative burden on providers, which can hamper our efforts to offer high-quality care to Medicare beneficiaries. ANNA supports the recommendations that have been submitted by KCP and the Alliance for Home Dialysis under this section and we provide additional comments on some of these topics.

Focusing on Quality Measures that Matter Most to Patient Outcomes

ANNA believes that CMS continues to propose an excessive number of measures. While each measure is important, they are not all priorities in the quality of care provided by dialysis units, and the quantity of measures dilutes the importance of measures that matter. ANNA asks that the agency lessen the burden on facilities, particularly on the nephrology nursing staff.
who are tasked with reporting much of this data, and prioritize for inclusion in the QIP evidence-based measures that will drive improvement in quality of patient care and health outcomes. Nephrology nurses spend more time with patients than any other member of the clinical team does, and they aim to provide the highest quality care to Medicare beneficiaries. When a nephrology nurse’s very limited time is spent collecting data on measures that are not directly related to the patient’s quality of care that time does not contribute to the improvement of patient outcomes. ANNA agrees with KCP that CMS should pause its current measure development efforts and instead focus on engaging with the entire stakeholder community on developing quality measures that would directly provide positive effects on our patients and their outcomes.

For example, in this comment letter and in previous communications with the Agency, ANNA has mentioned the importance of reducing catheters as an example of a clinically significant measure that competes against other measures that do not make significant differences in the quality of care. We have also mentioned the “survey fatigue” that our patients experience. ANNA members hear from patients constantly about the burden placed upon them by being asked to complete numerous surveys (e.g., ICH CAHPS twice annually, KDQOL, depression screening, and corporate satisfaction surveys). ANNA looks forward to working with the Agency to determine those specific measures that most drive improvement in quality of care and on ways to reduce the burden of the data that is required for the QIP on patients and providers, including nephrology nurses.

Conclusion

ANNA greatly appreciates the opportunity to share our comments on CMS’ proposed rule for the CY 2018 ESRD PPS, AKI payment, and QIP. As the leading professional association representing nephrology nurses, we look forward to continuing to work with your Agency on these important issues. Should you have any questions, please contact me or have your staff contact our Health Policy Representative, Jim Twaddell, at jim.twaddell@dbr.com or 202-230-5649. We thank you for your consideration.

Sincerely,

Alice Hellebrand, MSN, RN, CNN
ANNA President, 2017-2018